UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ASACOL ANTITRUST LITIGATION This Document Relates To: All End-Payor Actions	 Civil Action No. 1:15-cv-12730 (DJC) JURY TRIAL DEMANDED

END-PAYOR PLAINTIFFS' CONSOLIDATED

SECOND AMENDED CLASS ACTION COMPLAINT

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Plaintiffs Teamsters Union 25 Health Services & Insurance Plan, NECA-IBEW Welfare Trust Fund, United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund, Wisconsin Masons' Health Care Fund, Minnesota Laborers Health and Welfare Fund, and Mark Adorney bring this class action on behalf of themselves and all others similarly situated against Warner Chilcott Limited, Warner Chilcott plc, Warner Chilcott Company LLC, (together "Warner Chilcott") Allergan plc, Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC (collectively "Allergan" or the "Product Hop Defendants"). Plaintiffs allege the following based upon personal knowledge, investigation of counsel, and information and belief:[1]

I. NATURE OF THE ACTION

1. Asacol® (400mg) was a blockbuster ulcerative colitis drug. By 2004, it was one of the top 100 selling pharmaceuticals in the United States and was generating more than $300 million in yearly sales for Proctor & Gamble Pharmaceuticals, Inc. ("Proctor & Gamble"). By 2012, Warner Chilcott had acquired the rights to Asacol® (400mg) and sales had ballooned to over $570 million. Thousands of patients had come to rely on Asacol® (400mg) to treat ulcerative colitis and most patients intended to stay on the drug for life to keep their symptoms in remission. Proctor & Gamble, and later Warner Chilcott, were able to sell Asacol® (400mg) at supra-competitive prices during this period because two patents blocked other manufacturers from selling a generic version of the drug.

[1] End-Payor Plaintiffs previously brought claims for an alleged "reverse-payment" agreement between the current defendants, Zydus Pharmaceuticals USA Inc., and Cadila Healthcare Limited. On July 20, 2016, the Court dismissed End-Payor Plaintiffs' reverse payment claims. End-Payor Plaintiffs submit this Second Amended Consolidated Class Action Complaint without reverse-payment allegations for the Court's convenience to include only the current allegations at issue. End-Payor Plaintiffs do not waive the reverse-payment allegations and do not waive their right to appeal the Court's July 20, 2016 dismissal of those allegations.

2. This was all supposed to change on July 30, 2013, when the two patents on Asacol® (400mg) were set to expire. On that date, generic manufacturers would be able to compete for the first time. State substitution laws made it inevitable that Warner Chilcott would lose the majority of its sales to generic competitors who would sell Asacol® at a fraction of the brand price. Unfortunately, patients have never had access to generic Asacol® and continue to pay brand prices to this day. This action seeks to hold Warner Chilcott and Allergan (the recent successor to the Asacol® franchise) accountable for the unreasonable and illegal practices that they have employed and continue to employ to prevent generic competition for Asacol® (400mg).

3. Warner Chilcott employed a multi-faceted scheme to frustrate generic competition with its brand drug. First, Warner Chilcott developed two "new" versions of the drug: Asacol® HD and Delzicol®. Next, to prevent patients from staying on the original drug and then inevitably switching to the low cost generic, Warner Chilcott took the extreme step of removing Asacol® (400mg) from the market in the spring of 2013, shortly before its patents expired. This strategy, known as a "hard switch," frustrates generic competition by eliminating the prescription base for the original reference drug before generic competitors can establish market share. A "hard switch" forces most generic companies—like those prepared to launch generic Asacol—to abandon their efforts to attain FDA approval and enter the market. This anticompetitive maneuver is in direct conflict with the policies underlying the Hatch-Waxman Act, state generic drug substitution laws, and antitrust laws—all of which seek to facilitate drug price competition. In most states, the removal of the brand product effectively prevents consumers from access to a lower-priced generic because pharmacists may only automatically substitute a generic drug if it has been approved as an AB-rated equivalent formulation of the

referenced brand drug. Warner Chilcott was undoubtedly aware of this fact when it decided to withdraw Asacol® (400mg) from the market. Through the "hard switch," Warner Chilcott made sure that ulcerative colitis patients would be denied a generic Asacol® (400mg) option, and thus, would be forced to turn to Warner Chilcott's "new" formulations—Asacol® HD and Delzicol®. In a February 2013 investor conference call, Warner Chilcott's Chief Executive explained these market dynamics:

> Generally, the generic company doesn't even get launched because the reference product will be Delzicol. . . . There won't be any Asacol out there. We've seen that happen with Doryx, when the generic company got the product approved and by that time the product had moved on . . . . As the reference product has changed and then moved on to either tablet or new dose form, there really isn't much to be substituted there.[2]

As intended, the hard switch has had the anticompetitive effect of dissuading generic manufacturers from launching a competing version of Asacol® (400mg).

4. By removing Asacol® (400mg) from the market, Warner Chilcott interfered with consumer choice and forced thousands of ulcerative colitis sufferers to find a new treatment, at an increased cost. One patient expressed frustration and bewilderment at this turn of events:

> My doctor's office just called and told me they are discontinuing manufacturing Asacol. There is a new medicine called Delzicol. I was told it's the same medicine as Asacol but it's in a capsule. So I asked about the enteric coating and delivery mechanism but they didn't know. Does anyone have info on this? I am freaking out. :([3]

Another patient posted:

[2] Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript.

[3] *Asacol is being discontinued!*, HealingWell.com (April 1, 2013), *available at* http://www.healingwell.com/community/?f=38&m=2689473.

> No, No NO! I don't want to start on a new drug. This is ridiculous. I need to get off of this, total BS that they may be compromising people's health and symptoms over halting the manufacture process and pointing to a new drug in its place.[4]

Yet another patient remarked, "I have had 10 years remission with asacol, and like many here, BUMMED OUT about the greedy sub-humans who prey on us."[5]

5. Warner Chilcott removed Asacol® (400mg) from the market to force patients to its other ulcerative colitis products, Delzicol® and Asacol® HD. This effort was tremendously successful. Allergan (the company that recently purchased Warner Chilcott) sold approximately $550 million of Asacol®HD and Delzicol® in 2014; hundreds of millions of dollars more than what it would have sold had generic Asacol® (400mg) been available.

6. As a result of this scheme to thwart the federal and state regulatory system designed to enhance drug price competition, Allergan continues to reap *supra*-competitive profits on Asacol® HD and Delzicol® due to the absence of a generic Asacol® (400mg) product. But for Warner Chilcott removing Asacol® (400mg) in the spring of 2013, a generic version of the drug would have entered the market on or around the July 31, 2013 patent expiration. The generic product would have been automatically substitutable for 100% of the units of brand Asacol® (400mg). According to conservative estimates, generic competitors would have captured 80% to 95% of Asacol® (400mg) sales by July 31, 2014. Instead, Allergan continues to retain its original Asacol® (400mg) profits under the Delzicol® and Asacol® HD brands because the Product Hop Defendants' anticompetitive conduct has forcibly shifted Asacol® (400mg) sales volume to other products. Plaintiffs and thousands of other consumers and third-

[4] *Id.*
[5] *Id.*

party payers have paid hundreds of millions of dollars for brand Asacol® HD and Delzicol® when they would have purchased generic versions of Asacol® (400mg) at a fraction of the cost.

7. As explained in more detail below, Warner Chilcott's top executives have admitted that their scheme to unlawfully prolong and protect the Asacol franchise was not motivated by consumer welfare or safety concerns. Rather, the scheme was a mere "instrument" the Company used to achieve its singular goal of "sustaining the Asacol franchise." The scheme undermined the federal and state regulatory laws enacted to foster prescription drug competition by preventing pharmacists from automatically substituting brand Asacol® (400mg) prescriptions for its lower-priced generic equivalents. This suit, brought under state antitrust laws, seeks money damages on behalf of indirect purchaser "end-payor" plaintiffs who have been denied the right to purchase a generic version of Asacol® (400mg) as a result of Defendants' anticompetitive practices.

II. JURISDICTION AND VENUE

8. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of Allergan.

9. Venue is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), because Defendants transact business within this district, and/or have an agent and/or can be found in this district, and the inter and intrastate trade and commerce, described herein, is carried out in substantial part in this district.

10. Pursuant to relevant state statutes invoked below, Plaintiffs delivered a demand letter by certified mail to Allergan on June 22, 2015.

11. End-Payor Plaintiffs will provide notice of claims to the Arizona Attorney General, as required by Arizona Rev. Stat. § 44-1415(A), by sending a copy of this Complaint via certified mail on or around August 15, 2016.

12. End-Payor Plaintiffs will provide notice of claims to the Nevada Attorney General, as required by Nev. Rev. Stat. § 598A.210(3), by sending a copy of this Complaint via certified mail on or around August 15, 2016.

III. PARTIES

A. Plaintiffs

13. Plaintiff UFCW is an employee welfare benefit plan. UFCW's office, from which it pays medical benefits including benefits for prescription drugs, is located in Cook County, Illinois. During the Class Period, as defined below, UFCW purchased brand Asacol® (400mg), Asacol® HD, or Delzicol® during the Class Period in Florida, Illinois, and Missouri, and would have purchased generic Asacol® (400mg) and generic Asacol® HD had Product Hop Defendants not foreclosed generic competition for brand Asacol® (400mg) and Reverse Payment Defendants not foreclosed generic competition for brand Asacol® HD. UFCW paid more than it would have absent Defendants' unlawful schemes to prevent and delay generic entry.

14. Plaintiff Teamsters Union 25 Health Services & Insurance Plan is an employee health and welfare benefit plan. The Plan's office, from which it pays medical benefits including benefits for prescription drugs, is located in Suffolk County, Massachusetts. During the Class Period, as defined below, the Plan purchased brand Asacol® (400mg), Asacol® HD, or Delzicol® in Massachusetts, New Jersey, Missouri, and New Hampshire and would have purchased generic Asacol® (400mg) and generic Asacol® HD had Product Hop Defendants not

foreclosed generic competition for brand Asacol® (400mg). The Plan paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

15. Plaintiff NECA-IBEW Welfare Trust Fund is an employee health and welfare benefit plan. The Plan's office, from which it pays medical benefits including benefits for prescription drugs, is located in Macon County, Illinois. During the Class Period, as defined below, the Plan purchased brand Asacol® (400mg), Asacol® HD, or Delzicol® in Indiana, Missouri, Wisconsin, Alabama, Florida, Illinois, Kentucky, and Kansas and would have purchased generic Asacol® (400mg) had Product Hop Defendants not foreclosed generic competition for brand Asacol® (400mg). The Plan paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

16. Plaintiff Wisconsin Masons' Health Care Fund is a self-funded, multi-employer health welfare plan governed by the Employee Retirement Income Security Act of 1974 (ERISA), as amended. The Fund is administered by Benefit Plan Administration of Wisconsin at 2901 W. Beltline Highway, Suite 100, Madison, Wisconsin 53713-4226. During the Class Period, as defined below, the Fund purchased brand Asacol® (400mg), Asacol® HD, or Delzicol in Indiana and Wisconsin and would have purchased generic Asacol® (400mg) had Product Hop Defendants not foreclosed generic competition for brand Asacol® (400mg). The Fund paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry.

17. Plaintiff Minnesota Laborers Health and Welfare Fund is an employee welfare benefit plan. The Fund's office, from which it pays medical benefits including benefits for prescription drugs, is located in Minneapolis, Minnesota. During the Class Period, as defined below, the Fund purchased brand Asacol® (400mg), Asacol® HD, or Delzicol® in Minnesota, Ohio, and Wisconsin and would have purchased generic Asacol® (400mg) had Product Hop

Defendants not foreclosed generic competition for brand Asacol® (400mg). The Fund paid more than it would have absent Defendants' unlawful schemes to prevent and delay generic entry.

18. Plaintiff Mark Adorney is a natural person who resides in Beverly, Massachusetts. During the Class Period, as defined below, Mr. Adorney purchased brand Asacol® HD in Massachusetts. Mr. Adorney would have purchased generic Asacol® (400mg) had Product Hop Defendants not foreclosed generic competition for brand Asacol® (400mg). Mr. Adorney paid more than he would have absent Defendants' unlawful schemes to prevent and delay generic entry.

B. Defendants

19. Defendant Allergan plc ("Allergan") is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Allergan maintains a place of business within the United States at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Allergan was known as "Actavis plc" ("Actavis") until June 15, 2015, when it began operating under its current name. Allergan markets brand and generic pharmaceuticals throughout the United States and has commercial operations in the United States and approximately 100 countries around the world. The Company became a successor in interest to Warner Chilcott plc and Proctor & Gamble Pharmaceuticals Inc. when it acquired Warner Chilcott plc on October 1, 2013.

20. Allergan, Inc. is incorporated under the laws of Delaware, with its principal place of business at 2525 Dupont Drive, Irvine, California, 92612.

21. Allergan USA, Inc. is incorporated under the laws of Delaware, with its principal place of business at 2525 Dupont Drive, Irvine, California, 92612.

22. Allergan Sales, LLC is a California limited liability corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 92612.

23. Warner Chilcott Limited is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Bermuda with its principal place of business at Canon's Court 22, Victoria Street, Hamilton HM 12, Bermuda.

24. Warner Chilcott Company, LLC is an indirect wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Puerto Rico with its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

25. Upon information and belief, Defendants above transact business in the Commonwealth of Massachusetts but no Defendant maintains a place of business or keeps assets within the Commonwealth for the purposes of Mass. Gen. Laws Ann. ch. 93A, § 9.

IV. THE PRESCRIPTION DRUG REGULATORY FRAMEWORK

26. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), governs the manufacturing, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a company wanting to sell a new drug must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") and provide scientific data demonstrating that the drug is safe and effective for a specific indication. *See id.* § 355(b)(1). The process to obtain FDA approval for an NDA is long, comprehensive, and costly.

27. As compensation for this regulatory burden, drug manufacturers are allowed to protect their new products by listing applicable patents in the FDA's "Orange Book." *Id.* § 355(b)(1), (c)(2). The Orange Book, formerly known as "Approved Drug Products with Therapeutic Equivalence Evaluations," includes all FDA-approved prescription drugs, their approved generic equivalents, and any patents that purportedly protect each drug.

28. Drug patents typically last twenty years. *See* 35 U.S.C. § 154(a)(2) ("[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . . ."). The patent exclusivity period incentivizes drug innovation by allowing drug manufacturers to recoup their initial research and development costs and make a substantial profit on top.

29. Although the FDA lists patents in the Orange Book, it does not examine the validity of Orange Book patent submissions. Instead, the FDA performs a purely ministerial function—the FDA lists any patents that the NDA-holder claims cover its drug. *See Teva Pharmaceuticals, USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008) ("When it comes to the veracity of the patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information."). In other words, drug companies are free to list patents in the FDA's Orange Book as claiming a particular drug, without FDA scrutiny, subject only to subsequent patent challengers.

30. In addition to the ordinary patent term, the FDA has authority to grant manufacturers additional exclusivity periods to incentivize the development of particularly beneficial or necessary drugs. For instance, a manufacturer is eligible to receive five years of additional FDA exclusivity if it develops a "new chemical entity" ("NCE"); three years if it develops a new, but non-NCE product; and seven years if it develops a drug that treats a rare condition (*i.e.* an "orphan drug"). These periods of FDA exclusivity, beyond the ordinary patent term of twenty years, often compensate for unfairness in the ordinary patent process and incentivize the development of drugs in traditionally unprofitable markets.

31. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, to facilitate competition from low-price generic drugs while maintaining the incentive for companies to research and develop new products. *See Caro Pharm. Labs., Ltd. V. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (The Hatch-Waxman Act is "designed to speed the introduction of low-cost generic drugs." (internal citations omitted)). The Act permits generics to come to market soon as brand drugs lose patent protection and encourages generic manufacturers to challenge the scope and validity of existing brand patents.[6]

32. Once the FDA has approved a brand drug, the Hatch-Waxman Act allows a generic manufacturer to obtain similar approval by filing an Abbreviated New Drug Application ("ANDA") specifying that the generic has the same active ingredient and is "biologically equivalent" ("bioequivalent") to the reference brand drug. *See* 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). The ANDA application process allows generic manufacturers to rely on a reference drug's original clinical studies, thereby reducing the cost and time necessary to bring a generic drug to market.[7]

33. As a result, generic drugs cost 80-85% less on average than their brand counterparts.[8]

34. When a company seeks to market a generic counterpart to a brand drug, the company must certify that it will not infringe any of the patents listed in the Orange Book for the reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) ("[Each ANDA shall contain] a

[6] *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228-29 (2013).
[7] *See Actavis*, 133 S. Ct. at 2228.
[8] FDA Center for Drug Evaluation and Research, *The Lower Price Doesn't Mean Inferior*, at 2 (2012), *available at* http://www.fda.gov/Drugs/ResourcesForYou /Consumers/BuyingUsingMedicineSafely/Understanding GenericDrugs/ucm305896.htm.

certification, in the opinion of the applicant and to the best of his knowledge, with respect to each which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval under this subsection . . . .”). An ANDA-filer must certify that it will not infringe any patents claiming to cover the reference product because: (1) no patents are listed in the Orange Book; (2) all applicable patents have expired; (3) the applicant will not introduce a generic drug until all applicable patents have expired; or (4) all applicable patents are invalid or will not be infringed by the proposed generic product. *Id.* The fourth option is referred to as a “Paragraph IV Certification” and usually triggers litigation between the generic applicant and the NDA holder.[9]

35. Besides Hatch-Waxman, generic substitution laws in all fifty states and the District of Columbia also strongly encourage the use of generic drugs. These laws allow, and sometimes require, pharmacists to fill brand prescriptions with cheaper AB-rated generic equivalents, unless the prescribing physician directs otherwise.[10] An “AB-rated” generic drug is a generic equivalent drug determined by the FDA to meet strict bioequivalence testing standards basically showing that it has the same efficacy and safety profile as the referenced brand drug.

36. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by a brand manufacturer in order to extend its monopoly over a particular product. In most industries, the person who selects a product for purchase must also pay for that product. Therefore, normally,

[9] *Actavis*, 133 S. Ct. at 2228.

[10] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010). *See, e.g.*, N.Y. Educ. Law § 6816-a (McKinney) (“A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met . . . .”).

the price of the product plays a critical role in the consumer's choice of products and, consequently, sellers have a strong incentive to lower the price of their products to remain competitive.

37. The pharmaceutical marketplace, by contrast, suffers from a "disconnect" between payment obligation and product selection. The patient (and in many cases his or her insurer or Health Plan) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

38. Studies show that physicians typically are not aware of the relative costs of pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves. The result is a marketplace in which price plays a comparatively unimportant role in product selection and there is very little cross-elasticity of demand among differentiated products within a therapeutic class of drugs. This, in turn, gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales (unless, of course, there is an AB-rated generic of the brand drug available).

39. Many pharmaceutical manufacturers, including Warner Chilcott, exploit this feature of the pharmaceutical marketplace. Brand manufacturers employ armies of sales representatives, known as "detailers," who descend upon physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the brand products.

40. State substitution laws were specifically designed to fix the disconnect in the United States healthcare industry between the doctors who prescribe, but do not pay for, the drugs, and the individuals and institutions who pay for, but do not select, them.[11]

41. As a result of the public policy encouraging lower-priced generics, as codified in the Hatch-Waxman Act and state substitution laws, brand manufacturers typically lose 80-90% market share within one year of generic competition. The financial impact to brand drug sales due to patent expiration has become known as the "patent cliff." The patent cliff represents a serious and significant threat to the revenues of brand drug manufacturers:

a. According to a 2013 study, brand new molecular entities with sales of at least $250 million prior to generic entry retained only 11% of pre-generic sales one year after generic competition. Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ECON., Dec. 2013, at 1, 8.

b. The IMS Institute for Healthcare Informatics concluded, "Over 80% of a brand's prescription volume is replaced by generics within six months of patent loss . . ." *The Use of Medicines in the United States: Review of 2010*, at 3 (April 2011).

c. The former CEO of Forest Laboratories (which Allergan recently acquired and which is also currently being accused of product-hopping antitrust violations) acknowledged this fact during a recent deposition: "The entire healthcare system is designed to benefit generic companies and put up barriers and obstacles to the innovative companies, and so that's why you generally

[11] Carrier, *supra*, at 1017.

see the market shift 90/99 percent towards the generics." *New York v. Actavis, PLC*, No. 14-CIV-7473, 2014 WL 7015198, at *9 (S.D.N.Y. Dec. 11, 2014).

42. The only material difference between AB-rated generic drugs and their corresponding brand versions is their price. Because generic versions of a corresponding brand drug product are commodities that are not differentiated through advertising or other means, the primary basis for generic competition is price.

43. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two entirely undifferentiated generic products that compete solely on price. Conservative estimates show that a single generic launch results in a near term retail price reduction of around 10%, but that with two generic entrants, near term retail price reduction is about 50%.

44. Given the financial stakes tied to generic drug entry, brand companies have devised methods to frustrate the public policy in favor of generic competition by extending their product monopolies. For example, brand companies have entered "reverse payment" settlements with impending generic manufacturers. In these settlements, a brand manufacturer who holds a questionable patent compensates a potential generic rival to drop its patent challenge. In this way, both companies agree to split the brand manufacturer's monopoly profits. In 2013, the U.S. Supreme Court decided that this type of "reverse payment"—also known as a "pay for delay" settlement—could subject the participants to antitrust liability. *Actavis,* 133 S. Ct. 2223.

45. This case involves a practice called "product hopping," "ever greening," or "line extension," or—in Warner Chilcott's own parlance—"lily padding," which is a similar scheme to thwart expected generic competition. Although the AB-rating requirement for generic drugs is designed to ensure therapeutic-equivalence to the reference product, it is also subject to

manipulation by brand manufacturers seeking to maintain *supra*-competitive profits. Because the AB-rating requirement is so strict, the slightest tweak to the reference brand drug, such as switching from a tablet to a capsule, will prevent a generic equivalent to the original reference drug from obtaining an AB-rating to the "new" product. As such, pharmacists are not allowed to substitute a generic when presented with a prescription for the "new," slightly-modified brand drug, despite the fact that the old and "new" brand drugs are virtually identical in all respects. To further this scheme, the brand manufacturer often removes the original drug from the market entirely—known as a "hard switch"—right before patent expiration. This leaves potential generic manufacturer competitors that have developed safe, affordable generic drugs—which consumers desperately want—with no prescription base for the reference product. By removing the generic companies' only viable cost-efficient means of competing with brand drugs, the "hard switch product hop" strategy effectively prevents generic versions of the original drug from ever coming to market.

46. The effectiveness of "product hopping" is well-known within the pharmaceutical industry. Specifically, brand manufactures know that generic versions of brand drugs are not likely to ever come to market if the reference drug has been discontinued prior to patent expiration because the prescription base (and by extension the potential for automatic substitution) has been eliminated.

47. Recently, courts have decried the practice of hard switch product-hopping, finding it likely that plaintiffs can prove the conduct to be anticompetitive because "when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, its actions are anticompetitive under the

Sherman Act."[12] As the Second Circuit explained, by withdrawing its old product from the market, the manufacturer "crosses the line" from seeking to persuade physicians and patients to accept its "new" product, to coercing patients to switch to the "new" drug or risk grave medical conditions.[13] Hard-switch product hops impede competition by preventing generic substitution.[14]

48. The Third Circuit Court of Appeals is currently hearing an appeal from a generic manufacturer plaintiff seeking to hold Warner Chilcott liable under antitrust law for product-hopping on a different brand drug, Doryx. The generic manufacturer plaintiff-appellant's position was supported by *amici curiae* briefing from the Federal Trade Commission, American Antitrust Institute, AARP, Consumers Union, Consumer Action, Consumer Federation of America, Families USA, National Health Law Program, Center for Medicare Advocacy, United States Public Interest Research Group, and seven of the nation's leading antitrust and intellectual property professors.[15]

49. An authorized generic is essentially the same as the brand drug but in a different package: it is chemically identical to the brand drug, and manufactured under the brand name drug's NDA, but sold as a generic product—often through either a brand manufacturer's subsidiary (if it has one) or through a third-party distributor. Competition from an authorized

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[12] *New York* ex rel. *Schneidermann v. Actavis plc* ("*Namenda*"), 787 F.3d 638, 654 (2d Cir. 2015); *see also In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014) (finding plaintiffs had adequately pleaded an antitrust violation by alleging a product hop, after observing "[t]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit");

[13] *Namenda*, 787 F.3d at 654.

[14] *Id.* at 655.

[15] *See Mylan Pharmaceuticals Inc. v. Warner Chilcott, et al.*, No. 15-2236 (3d Cir. 2015) (*amici* briefs filed in support of Plaintiff-Appellant on Sept. 30, 2015).

generic substantially reduces drug prices and the revenue of the first-filer generic. If the first-filer generic has regulatory or *de facto* exclusivity, an authorized generic reduces the revenue of the first-filer generic by at least half. In other words, the absence of an authorized generic can more than double the first-filer's revenue.

50. Authorized generics are priced like other generics and compete on price with other generics. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[16] A study analyzing three examples of authorized generics found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[17]

51. Although civil litigation often ends with settlement that includes the transfer of something of value from the defendant to the plaintiff, in a reverse payment settlement, the *plaintiff* instead pays the *defendant*. That is, a brand manufacturer pays a generic manufacturer to delay or abandon market entry, and to abandon the challenge to the validity of the brand drug company's patent or patents. Such settlements are anticompetitive; the brand companies unlawfully maintain monopoly profits and effectively split them with generic companies in return for generic delay. Plaintiffs and the putative Class end up paying for it all, or, as the Supreme Court has put it: "The patentee and the challenger gain; the consumer loses."[18]

[16] Hassett, K. A. and R. J. Shapiro, "The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals," Sonecon, May 2007, p. 3.
[17] Berndt, E., R. Mortimer, A. Bhattacharjya, A. Parece and E. Tuttle, "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," Health Affairs, v. 26, n. 3, May/June 2007, p. 796.
[18] *Actavis*, 133 S. Ct. at 2235.

52. A first-filer generic, in particular, can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of its 180-day period of generic market exclusivity. This tactic—sometimes referred to as "parking exclusivity"—creates a bottleneck because later generic applicants cannot launch generic versions of the product until the first-filer generic applicant's 180-day exclusivity has elapsed or is forfeited. Thus, settlements between brand and first-filer generics provide a strong disincentive against generic product development by other generic manufacturers.

53. The market disincentives are even more pronounced when the reverse payment agreement includes provisions that allow the first-filer generic to enter the market earlier than otherwise agreed with the brand manufacturer *if* a subsequent generic manufacturer succeeds in entering the market. These provisions are called "acceleration clauses." The co-conspirators disclose these terms publicly, broadcasting to subsequent filers that even if they incur the substantial expense involved in dislodging the "parked exclusivity" bottleneck, they will immediately face competition from at least the first-filer generic.

54. By eliminating all possibility that subsequent filers will enjoy any period of *de facto* exclusivity, acceleration clauses significantly reduce the value to subsequent filers of obtaining a court decision of patent invalidity or non-infringement—findings that would break the first-filer bottleneck. Thus, where a first filer has "parked" its 180-day exclusivity and agreed to such a provision, subsequent filers have substantially less to gain by continuing to pursue development, patent litigation, and market entry of the drug in question.

55. Drug companies commonly disguise reverse payment agreements by cloaking the bribe as a promise from the brand manufacturer to refrain from launching an authorized generic

version of a drug when the parties agree that the generic competitor can bring its product to market. Because the availability of an authorized generic severely diminishes the profitability to a generic manufacturer of launching its own version of a drug, a brand manufacturer's agreement not to launch an authorized generic has tremendous financial value to a first-filer generic manufacturer.

56. Payment to the first-filer generic company in the form of a no-authorized generic agreement is economically equivalent to a cash payment by the brand manufacturer because the agreement effectively doubles (or more) the revenues and profits of the generic company. The brand manufacturer foregoes the substantial sales and revenue that it otherwise would make with its own authorized generic, but in return for allocating all generic sales to the generic company, the brand manufacturer can obtain a later generic entry date from the generic company. The brand manufacturer wins because it maintains monopoly profits on its brand drug longer than it otherwise would without bribing the generic company, and the generic company wins because it will enjoy *supra*-competitive generic profits itself when it does enter the market at a later date. Payers, however, lose; generic drug availability is delayed, and when it finally comes (if it comes at all), it is more expensive than it should be because the brand manufacturer and generic company have already allocated the market.

57. For a generic first-filer of a brand product that sold hundreds of millions of dollars annually, like Asacol® HD, the difference between selling a generic product without having to compete against an authorized generic and competing with such an authorized generic amounts to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-authorized-generic agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to

them from increased competition. Thus, No-AG reverse payments are even worse for consumers than cash reverse payments because consumers are overcharged twice in No-AG agreements: once during the period of generic delay, when consumers are forced to pay for the brand instead of the generic, then again when the authorized generic is withheld from the market and the available generic is priced higher than it should be because it faces no competing generic price pressure.

58. For this reason, courts that have considered the effects of No-AG promises have almost universally found such promises to violate the antitrust laws under *Actavis*.[19] As the Third Circuit—the first appellate court to consider whether a No-AG promise may constitute a reverse payment under *Actavis*—explained: "[N]o-AG agreements are likely to present the same types of problems as reverse payments of cash," because they are sufficiently valuable to generic companies to induce the generic companies to abandon their challenge to weak or invalid patents and refrain from competing in the market.[20]

[19] *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* ("*Lamictal*"), 791 F.3d 388, 403 (3d Cir. 2015) (holding that no-AG agreements may constitute payments under *Actavis*); *In re Aggrenox Antitrust Litig.*, No. 14-md-2516, 2015 U.S. Dist. LEXIS 35634 (D. Conn. Mar. 23, 2015) (holding that defendants "clearly agree" that a no-AG promise "is very valuable" and recognizing "[a] majority of courts to have examined the issue" have ruled "that 'payment' is not limited to cash transfers"); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) ("I agree with the bulk of the recent decisions holding that courts need not restrict the definition of 'payments' under *Actavis* to cash."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014) (finding "the term 'reverse payment' is not limited to a cash payment" and holding that a "no-AG clause itself" is a "reverse payment"); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014) ("[R]everse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments"); *see also King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, No. 06-cv-1797, 2015 WL 356913, at *15-16 (E.D. Pa. Jan. 28, 2015) (analyzing reverse payment settlements under *Actavis* and finding that jury could conclude that side deals were simply a means of providing payments for delay and/or inducing generics to stay off market).

[20] *Lamictal*, 791 F.3d at 404.

V. ANTICOMPETITIVE SCHEME TO AVOID GENERIC ENTRY

A. Ulcerative Colitis and Asacol®

59. Ulcerative colitis is a chronic inflammatory bowel disorder that typically causes bloody diarrhea, rectal urgency, tenesmus, and abdominal cramping. The disorder may also affect the skin, eyes, joints or livers of ulcerative colitis sufferers. The condition is present in 238 out of 100,000 people in the United States. If inflammation persists or is left untreated, ulcerative colitis increases the risk of colorectal cancers.

60. Ulcerative colitis is traditionally a cyclical disorder, meaning patients are often without symptoms for periods of time but will then occasionally develop another ulcer (*i.e.* have another "flare"). This disease cycle requires two modes of treatment. Patients use one mode of treatment to treat active ulcerative colitis flares and another mode of treatment to keep flares from returning. This second type of treatment is known as "maintenance of remission" therapy.

61. The most common treatment for ulcerative colitis is a class of drugs containing the active ingredient mesalamine, which is in a therapeutic class of drugs containing 5-aminosalicylic acid or 5-ASA—a derivative of salicyclic acid closely related to aspirin.

62. Mesalamine drugs operate topically, meaning they reduce inflammation upon contact with the inflamed portion of the colon, not from systematic changes to the body. Mesalamine formulations primarily differ as to where the active ingredient is released along the gastrointestinal tract. If the mesalamine is released too early—in the stomach or small intestine—then the active ingredient may not reach the colon and will not provide relief. If the mesalamine is released too late, much of the ingredient will pass through the body, again offering no relief.

63. The first effective oral mesalamine preparation, Salofalk®, was introduced by Dr. Falk Pharma in 1984. This product was able to deliver mesalamine to the colon because it was

protected from absorption in the upper gastrointestinal tract by a PH-sensitive, proprietary acrylic coating called Eudragit® L. This coating delayed release of the active mesalamine until was exposed to a pH 7, later in the gastrointestinal tract, and allowed the mesalamine to remain intact while it passed through the highly acidic stomach (which has a pH of 1.5 to 3.5).

64. Proctor & Gamble submitted NDA No. 19-651 to market a delayed-release oral tablet containing 400 mg of mesalamine. This drug, sold under the name brand Asacol®, was approved on January 31, 1992 to treat mild to moderately active ulcerative colitis. On August 19, 1997, the drug received an additional FDA indication for the maintenance of the remission of ulcerative colitis.

65. Asacol® (400mg) was a specific controlled-release mesalamine formulation that contained a special acrylic-based resin coating called Eudragit® S, which was sold by German pharmaceutical company Evonik Rohm GmbH. Eudragit® S was designed to dissolve in alkaline environments, at a pH greater than 6, such as the intestines, but not to dissolve in acidic environments such as the stomach. The enteric coating ("enteric" meaning "of the small intestine") allows Asacol® (400mg) tablets to pass through the stomach largely intact and then release active mesalamine directly into the affected areas.

66. Proctor & Gamble listed two patents in the FDA's Orange Book for Asacol® (400mg), U.S. Patent No. 5,541,170 ("the '170 patent") and 5,541,171 ("the '171 patent"). Both patents expired July 30, 2013.

67. Although Proctor & Gamble listed these patents in the Orange Book, another company, Medeva Pharma Suisse A.G. ("Medeva"), owned these patents and licensed them to Proctor & Gamble for use in connection with Asacol® (400mg). Medeva acquired these patents as the successor in interest to the original assignee, Tillots Pharma AG.

68. The U.S. Patent and Trademark Office granted the '170 and '171 patents on July 30, 1996. Proctor & Gamble then became the exclusive licensee of the '170 and '171 patents, which gave Proctor & Gamble the exclusive, unlimited and unrestricted right to develop, make, sell, and import the covered delayed release mesalamine tablets in the United States and other territories.

69. By 2004, Asacol® (400mg) was one of Proctor & Gamble's best selling prescription products. The drug became one of the top 100 selling pharmaceuticals in the United States that year with sales of approximately $322 million.

B. Introduction and Promotion of Asacol® HD

70. As with many patent-protected drug products, Proctor & Gamble knew that its enormous Asacol® (400mg) profits would end when the applicable patents expired on July 30, 2013. On that date, competitors would begin to sell generic Asacol® (400mg) at lower prices, and would quickly capture most sales volume, as intended by the Hatch-Waxman Act and state substitution laws. Thinking ahead, Proctor & Gamble developed a strategy to retain sales and extend the Asacol monopoly beyond the period provided by the '170 and '171 patents.

71. Around October 24, 2004, Proctor & Gamble submitted NDA No. 21-830 for an 800 mg, long-acting mesalamine tablet that was later marketed as "Asacol® HD." Asacol® HD was approved by the FDA on May 29, 2008.

72. Asacol® HD received FDA approval exclusively for the treatment of moderately active ulcerative colitis. Unlike Asacol® (400mg), this new drug was not approved for the treatment of the less severe conditions—mildly active ulcerative colitis or maintenance of remission of ulcerative colitis.

73. Proctor & Gamble listed two new patents in the Orange Book for Asacol® HD, U.S. Patent No. 6,893,662 and 8,580,302. Both of these will expire November 15, 2021.

74. Critical to Proctor & Gamble's maintenance of the Asacol® franchise, Asacol® HD was not AB-rated to the original Asacol® (400mg). Thus, under state substitution laws, pharmacists were not allowed to automatically fill a prescription for Asacol® HD with a generic version of the original Asacol® (400mg) product.

75. As a result, Proctor & Gamble knew that patients who were prescribed Asacol® HD would only be able to fill their prescriptions with Asacol® HD, at brand prices, even after generic versions of Asacol® (400mg) could enter the market in July 2013.

76. In the summer of 2009, Proctor & Gamble announced that it would sell its brand pharmaceutical division to Warner Chilcott. Warner Chilcott formally acquired Proctor & Gamble's interests in Asacol® (400mg) and Asacol® HD on October 30, 2009.

77. When Warner Chilcott acquired Asacol® (400mg), the drug was an immensely successful product. In 2009, the drug was the 75th top-selling prescription in the United States, with sales of approximately $490 million.

78. At this time, the conventional wisdom was that Asacol® (400mg) had less than four years of immense profitability remaining before generic entry in the summer of 2013. The CEO of Warner Chilcott, Roger Boissonneault, had other plans. The main purpose of acquiring Proctor & Gamble's pharmaceutical division, according to Boissonneault, was to acquire Asacol® (400mg) because the Company thought it could game state substitution laws, the Hatch Waxman Act, and the FDA's overall regulatory structure to prevent a generic version of Asacol® (400mg) from ever coming to market.

79. Boissonneault explained this "life cycle" management strategy during a 2012 conference call:

> It is worth mentioning here that when we acquired Proctor and Gamble's Pharma business, the asset we covered it was Asacol, and that was in large part because we

> believe the uncertain and potentially difficult regulatory pathway for generics could mean that Asacol may enjoy market exclusivity beyond the expiry of the patents around the brand. Based on events that have transpired since we acquired Asacol, we continue to be confident in the prospects for sustaining the Asacol franchise.
>
> Of course, one of the other elements of the Asacol franchise that appeals to us, was that the product lend themselves to the development of product improvements that are right in our sweet spot. So I would not expect that we would sit still with Asacol and hope to sustain it over the long haul. You should expect us to actively manage the life cycle of this important franchise.

Warner Chilcott CEO Discusses 2012 Guidance (Transcript), Jan. 27, 2012, *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript. In other words, Warner Chilcott acquired the Asacol® franchise because the Company thought it could continue to receive *supra*-competitive profits well into the future by throwing roadblocks in front of aspiring generic competition, thwarting the federal and state regulations that encourage the use of generic drugs.

80. Beginning shortly after the 2009 acquisition, Warner Chilcott exerted extraordinary efforts to switch patients from original Asacol® (400mg) to Asacol® HD. The Company hoped these patients would stay on Asacol® HD long after a generic version of Asacol® (400mg) came to market in July 2013.

81. The Company knew this strategy, which depended on patients staying on a particular formulation for extended periods, could be particularly effective with Asacol® patients. Ulcerative colitis is a lifelong condition and ulcerative colitis patients like to stay on a single drug once they find one that works. Patients prefer not to risk unnecessary symptoms by switching drugs. Boissonneault specifically recognized this feature of the Asacol® market:

> [W]hen someone is put on Asacol for their ulcerative colitis, it is likely that they put on the product 20 to 30 years old, and they are probably going to be taking that product for the rest of their lives, because it prevents the disease, and every once in a while they get a flare, and then you have to use corticosteroids to bring it back,

> and they certainly become – I mean it is indeed a great product but it is a product that is used in the long term.

Warner Chilcott CEO Discusses 2012 Guidance (Transcript), Jan. 27, 2012, *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript.

82. Unfortunately for Warner Chilcott's plans, Asacol® and Asacol® HD were not approved to treat the same conditions. Thus, Warner Chilcott could not legally market Asacol® HD to all Asacol® (400mg) patients. Asacol® (400mg) was approved to treat three different conditions: mildly active ulcerative colitis; moderately active ulcerative colitis; and, the maintenance of remission of ulcerative colitis. Asacol® HD was approved only to treat moderately active ulcerative colitis. The biggest difference is that Asacol® (400mg) was approved for low-dose, long-term maintenance of remission therapy, which accounts for the bulk of Asacol® (400mg) prescriptions. Asacol® HD was approved only for the high-dose, short-term treatment of the most severe flares.

83. Proctor & Gamble initially submitted Asacol® HD as a superior treatment for mildly and moderately active ulcerative colitis as compared to Asacol® (400mg). After poor clinical results, Proctor & Gamble reduced its proposed indication for Asacol® HD to treat only moderately active ulcerative colitis. Proctor & Gamble also changed its goal from demonstrating "superiority" over the original formulation to demonstrating "noninferiority" to the original product. Proctor & Gamble never attempted to get Asacol® HD approved for maintenance treatment of remission of ulcerative colitis.

84. The different indications meant that Warner Chilcott was legally prohibited from promoting Asacol® HD to treat mildly active ulcerative colitis or maintenance of remission therapy, which made up the bulk of Asacol® (400mg) prescriptions.

85. Despite the lack of scientific evidence, Warner Chilcott began an aggressive marketing campaign to switch patients from Asacol® (400mg) to Asacol® HD. This was the Company's top priority throughout 2010 and 2011. Boissonneault, responding to a question about the ongoing patient shift, revealed his plan to entirely disregard the two drugs' different indications:

> I think we lost a little bit of focus in the fact that convincing clinicians that you shouldn't use the 400 you should be using the HD. The issue is the reason that you use Asacol is not because it's 400 milligrams or 800 milligrams. The fact is that it works quickly, it's well tolerated and you can virtually take this for a long period of time.

Warner Chilcott PLC's CEO Discusses Q2 2011 Results – Earnings Conference Call (Transcript), Aug. 5, 2011, *available at* http://seekingalpha.com/article/285263-warner-chilcott-plcs-ceo-discusses-q2-2011-results-earnings-conference-call.

86. Later in the same conference call, Boissonneault talked about how the Company executed the switch: "If you go back and look at it and we – what happened was we took some [dermatology sales representatives] and we took some [gastrointestinal sales representatives] and put them together it was like a simplistic execution: Just move the 400 milligram to the HD." *Id.*

87. Warner Chilcott's effort to switch patients to Asacol® HD has already come under legal scrutiny. In March 2011, two former Warner Chilcott employees (who were inherited in the P&G acquisition) filed a *qui tam* action and accused the company, in part, of conducting a widespread off-label marketing campaign to switch Asacol® (400mg) patients to Asacol® HD in violation of federal law. Plaintiffs' Third Amended Complaint at 3-4, *United States ex rel. Alexander v. Warner Chilcott PLC, et al.*, No. 11-cv-10545 (D. Mass Aug. 8, 2013), ECF No. 45.

88. Most troubling for present purposes, the *qui tam* plaintiffs alleged that Warner Chilcott deliberately misrepresented the clinical evidence supporting Asacol® HD as part of its effort to switch patients to the new formulation before the '170 and '171 patents expired. As extensively alleged in the *qui tam* complaint, it was the Company's policy to convince doctors to prescribe Asacol® HD for all ulcerative colitis patients, not just those with moderately active ulcerative colitis—its approved indication. *See id*. at 151-158.

89. These private *qui tam* allegations were ultimately resolved as part of an October 2015 settlement between the U.S. Attorney for the District of Massachusetts, the U.S. Department of Justice, and Warner Chilcott subsidiary, Warner Chilcott Sales (U.S.) LLC.

90. In the settlement, Warner Chilcott agreed to plead guilty to felony healthcare fraud (18 U.S.C. § 1347) in the U.S. District of Massachusetts regarding allegations of overly aggressive marketing practices between October 2009 and September 2013. Warner Chilcott agreed to pay a criminal fine of $20.94 million, forfeit $2 million in assets, and settle civil allegations for $102.06 million.

91. As part of the felony plea, Warner Chilcott admitted that its sales representatives compensated doctors who prescribed high amounts of Warner Chilcott products with so-called "Medical Education Programs," which were in reality high-priced dinners on the Company that contained no medical education, and "Speaker Roundtables," which were pretexts to compensate high prescribing physicians with "speaking fees." Warner Chilcott also agreed that it had instructed its sales representatives to submit fraudulent prior authorizations, which allowed physicians to prescribe Warner Chilcott products despite insurance formulary restrictions. Additionally, Warner Chilcott agreed that it had fraudulently disseminated false and misleading scientific information suggesting that its product Actonel® was superior to lower priced

alternatives. Notably, Warner Chilcott also acknowledged that its overall corporate culture was hyper-aggressive and reckless during this period. As contained in the Information, Warner Chilcott preferred to hire young, assertive sales representatives (described as "Type A, crazy") with no experience in medical sales and even sought such individuals through "a personality test designed to highlight candidates who were aggressive and not sensitive to rules" who could then be counted on to uphold the hyper-aggressive "Warner Chilcott way." Company executives referred to those who would not adhere to this culture, many of whom were legacy P&G employees, as "creampuffs."

92. In addition to charges against the company, the President of Warner Chilcott Pharmaceuticals Division from 2009 to 2011, Carl Reichel, was also personally indicted for Conspiracy to Violate Anti-Kickback Statutes (18 U.S.C. § 371) in October 2015. The indictment contained allegations that Warner Chilcott engaged in hyper-aggressive and fraudulent marketing practices to promote its products, including Asacol® HD.

93. Warner Chilcott received a second benefit from aggressively switching patients to HD; patients prescribed Asacol® HD typically took 15% more milligrams of the drug. The Executive Vice President of Warner Chilcott, Paul Herendeen, explained this fact to investors in a 2012 earnings call. Regarding a discrepancy in prescription volume, Herendeen explained:

> One thing you do have to take into account . . . is to the extent that someone has an HD Rx versus a 400 Rx, they tend to use more mg per day. It's around 15% more per day. So there is that element, to the extent that you look at the franchise, and you look at HD, an HD Rx is kind of worth 1.15 of an Asacol 400 Rx.

Warner Chilcott Limited's CEO Discusses Q3 2012 Results – Earnings Call Transcript, Nov. 9, 2012, *available at* http://seekingalpha.com/article/995041-warner-chilcott-limiteds-ceo-discusses-q3-2012-results-earnings-call-transcript.

94. An Asacol® HD tablet was typically priced right around twice the cost of an Asacol® (400mg) tablet. Twice the price for twice the dosage. When patients switched drugs, they generally consumed 15% more mesalamine than they would have on original Asacol. This increased costs by 15% even though Asacol® HD has exclusively been approved based on "noninferiority" to the original product.

95. Warner Chilcott's push to Asacol® HD thus exposed patients to greater health risks. When these patients consumed 15% more milligrams of Asacol® HD, they were exposed to 15% more mesalamine for absolutely no medical reason. Similar to most prescription medications, a number of health risks are associated with Asacol® (400mg) and Asacol® HD. Asacol® HD, in particular, is specifically associated with liver and kidney failure. When Warner Chilcott switched patients from the low-dose to the high-dose formulation, for no legitimate medical reason, it likely exacerbated these health risks and potentially harmed some patients.

96. Warner Chilcott's effort to switch patients to Asacol® HD prior to expiration of the '170 and '171 patents was remarkably successful, especially in light of the fact that Asacol® HD is *not* approved for maintenance therapy—which accounts for the bulk of ulcerative colitis prescriptions. In 2010, Asacol® HD made up 9% of Warner Chilcott's total Asacol® franchise sales. By 2012, as a direct result of Warner Chilcott's sustained off-label marketing campaign, Asacol® HD sales constituted 28% of the Company's Asacol® franchise.

C. Citizen Petitions to Drive Up the Cost of Generic Entry

97. Warner Chilcott also submitted multiple FDA Citizen Petitions to make it harder for other manufacturers to sell generic Asacol® (400mg).

98. A "Citizen Petition" allows individuals and organizations to express concerns to the FDA about the safety, efficacy, or legality of a proposed or existing pharmaceutical. *See* 21

U.S.C. § 355; 21 C.F.R. 10.30. This process can be abused by competitors in the pharmaceutical industry to raise unfounded scientific or safety concerns, and thereby delay FDA approval.

99. Warner Chilcott considered Citizen Petitions to be another "instrument" in its arsenal to thwart generic competition. Roger Boissonneault described the company's comprehensive strategy:

> [] I think you have to employ multiple strategies along these lines, one certainly being the citizen's petition route. And there's other strategies that we can employ to make sure that we can defend the Asacol franchise because indeed it's an important franchise to us, but I really don't think that a generic can mimic the efficacy of the current product. So we believe the [citizens petition] is a good instrument, but it's not our only instrument.

Warner Chilcott Limited's CEO Discusses Q3 2012 Results – Earnings Call Transcript, Nov. 9, 2012, *available at* http://seekingalpha.com/article/995041-warner-chilcott-limiteds-ceo-discusses-q3-2012-results-earnings-call-transcript.

100. On February 22, 2010, Warner Chilcott submitted a Citizen Petition that requested the FDA to require generic Asacol® (400mg) applicants to submit, as condition precedent to FDA approval, comparative clinical endpoint studies, comparative in vitro dissolution tests, and comparative pharmacokinetic (PK) safety testing under fed and fasted conditions. *See* Warner Chilcott Citizens Petition, Docket No. FDA-2010-P-0111 (Feb. 22, 2010).

101. The first of these proposed requirements was the most controversial. Clinical endpoint studies would have required generic manufacturers to conduct their own long-term clinical tests to measure their proposed drug's effectiveness. This would have added millions of dollars onto the cost to develop a generic Asacol® (400mg) and—most importantly for Warner Chilcott—would have substantially delayed FDA approval of generic competitors.

102. The FDA denied Warner Chilcott's request for clinical endpoint studies in its August 20, 2010 response and concluded that "comparative clinical endpoint bioequivalence studies would be less sensitive, accurate, and reproducible than [other types] of studies." This response cited FDA regulations that say clinical studies are "the least accurate, sensitive, and reproducible of the general approaches for determining . . . bioequivalence" and they may be "considered acceptable only when" none of the other methods is available. *See* 21 C.F.R. 320.24(b)(4).

103. Undeterred, Warner Chilcott submitted another Citizen Petition dated October 14, 2012. Again, Warner Chilcott requested that the agency establish heightened bioequivalency requirements for generic competitors to Asacol® (400mg) and Asacol® HD.

104. Again, the FDA denied Warner Chilcott's request for heightened requirements and rebuked the company, stating "you provide no data or analysis in support of your assertion that [the existing standard]" would allow "early absorption in the upper GI tract."

105. While clearly intended to delay the introduction of generic Asacol® (400mg), Warner Chilcott's Citizen Petitions were largely unsuccessful. Warner Chilcott had to rely on other "instruments."

D. Introduction and Promotion of Delzicol®

106. Even after switching some patients to Asacol® HD, Warner Chilcott was still expected to lose the vast majority of its Asacol® franchise once its two original patents expired on July 30, 2013. The market sent a clear message to Warner Chilcott: patients and prescribers did not prefer the new formulation to Asacol® (400mg), as sales of the original product still constituted 72% of the overall franchise in 2012. Thus, despite a concerted three-year effort to switch patients to Asacol® HD, Warner Chilcott could not convince most patients and prescribers that Asacol® HD was an improvement over Asacol® (400mg). Further, the retained

sales of Asacol® (400mg) showed that even if the Company switched 50% of Asacol® (400mg) patients to the new Asacol formulation by the summer of 2013, it would still lose hundreds of millions of dollars to generic competition.

107. On July 31, 2012, Warner Chilcott submitted NDA No. 204412 for a new mesalamine product, which it later sold under the brand-name Delzicol®. The FDA approved Delzicol® for sale six months later on February 1, 2013.

108. Warner Chilcott touted Delzicol® as a significant improvement to investors and the general public. During an investor call in early 2013, Warner Chilcott's CEO bragged about the Company's ability to innovate: "The approval of Delzicol, our new 400-milligram delayed-release mesalamine product, provides you with tangible evidence of our ability to successfully develop improved versions of our key product." Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript.

109. In reality, Delzicol® was granted FDA approval based on its bioequivalence to Asacol® (400mg). Warner Chilcott established bioequivalence by submitting a comparative pharmacokinetic study and comparative dissolution studies showing that Delzicol® would act similarly to Asacol® (400mg) in the human body. Warner Chilcott did not conduct additional clinical efficacy trials or additional safety trials in support of its Delzicol® application.

110. Because Delzicol® is essentially the same as Asacol® (400mg) and did not entail substantial, beneficial investment, Warner Chilcott did not receive an additional period of FDA exclusivity for its new product.

111. Warner Chilcott identified only two differences between Asacol® (400mg) and Delzicol® in its FDA submissions: (1) Delzicol® consists of a cellulose capsule around an Asacol® (400mg) tablet; and (2) Delzicol® contains dibutyl sebacate ("DBS") as an inactive coating ingredient, while Asacol® (400mg) contains dibutyl phthalate ("DBP") instead.

112. Warner Chilcott included the cellulose capsule to give Delzicol® additional patent protection and to manipulate the regulatory system, not for any legitimate medical reason.

113. The new cellulose capsule on Delzicol® is covered by U.S. Patent No. 6,649,180 ("the '180 patent"), which expires April 13, 2020. The '180 cellulose tablet patent was originally published by the U.S. Patent and Trademark office over a decade before on November 18, 2003. The '180 patent claims a specific "hard capsule formed of cellulose ether film with a specific content of methoxyl and hydroxypropoxyl groups." This patent relates to the new capsule surrounding Delzicol® and is not related to the drug's active ingredient.

114. But for the '180 patent, generic manufacturers would have been able to sell generic Delzicol® as soon as it was introduced and a generic Delzicol® would be on the market today.

115. Several facts establish the cellulose capsule that triggers Delzicol®'s patent protection until 2020 is entirely unnecessary, does not provide additional therapeutic benefits, and was included only to further the monopolization scheme.

116. *First*, Delzicol® was approved exclusively on the basis of equivalence to Asacol® (400mg). This eliminates the possibility that the Delzicol® capsule makes the overall product medically superior to Asacol® (400mg).

117. *Second*, the hyrdroxpropyl methylcellulose ("HPMC") capsule around Delzicol® quickly dissolves in stomach acid. *See* Chiwele, et al., *The Shell Dissolution of Various Empty*

Hard Capsules, 48 CHEM. PHARM. BULL 951, 956 (2000) ("In any dissolution medium with pH below or equal to 5.8, MPMC capsules dissolve rapidly . . . ."); U.S. National Library of Medicine, National Institutes of Health, MedlinePlus, *Stomach Acid Test*, http://www.nlm.nih.gov/medlineplus/ency/article/003883.htm ("Normally . . . the pH [of the stomach] is acidic (1.5 to 3.5)."). Thus, the cellulose capsule likely provides no protection to the enteric-coated Asacol® tablet underneath. Enteric coatings are designed to protect active drug ingredients from stomach acid so these ingredients can be released in the less-acidic or alkaline environment later in the gastrointestinal tract. Cole et al., *Enteric Coated HPMC Capsules Designed to Achieve Intestinal Targeting*, 231 INT. J. OF PHARMACEUTICS 83, 83 (2002). Taken together, this means that the HPMC capsule surrounding the Delzicol® tablet is a nullity because the enteric coating on the inner-Asacol® (400mg) tablet prevents the mesalamine from releasing anyways.

118. *Third*, the capsule was not a required modification to include DBS instead of DBP as an inactive ingredient. Allergan currently sells a DBP-free 400 milligram Asacol tablet in the United Kingdom. *See* Package Leaflet: Information for the User, Asacol ® 400mg MR Tablets (mesalamine), last approved October 2014. The product is obviously a tablet. Thus, Allergan could manufacture DBP-free tablets without a new "capsule" formulation. According to the U.K. drug's label, the product contains dibutyl sebecate (*i.e.* DBS), but not dibutyl phthalate (DBP). *Id.* Thus, a Warner Chilcott or Allergan foreign subsidiary appears to have successfully removed DBP from its identical mesalamine product in the United Kingdom without adding a cellulose capsule. Upon information and belief, the company did not introduce a "new" capsule product in the United Kingdom, as it did in the United States with Delzicol®, because this

unnecessary feature would not allow the company to game the UK regulatory system as it did the U.S. system.

119. Further, the unnecessary Delzicol® capsule has made the product more difficult to swallow than the original formulation for many patients. In April 2014, the FDA issued an Addendum Clinical Review that summarized patients' difficulties swallowing Delzicol® compared to Asacol® (400mg). The document referenced 49 instances where patients had difficulty swallowing Delzicol® compared to 18 reported instances where patients had difficulty swallowing Asacol® (400mg) or Asacol® HD.

120. The fact that many patients find Delzicol® capsules difficult to swallow also meant that Delzicol® could not receive an FDA indication for the treatment of ulcerative colitis in those younger than 12 years old. While Warner Chilcott received a pediatric indication for Delzicol® in patients 12 and over based on previous Asacol® (400mg) pediatric studies, the FDA did not allow Warner Chilcott to use these same studies to establish safety and efficacy in children under 12 because the Delzicol® capsule may be too large for this population to swallow. The FDA summarized its conclusion:

> Because the approved Delzicol capsules are large compared to Asacol 400 mg tablets used in the Clinical trials and there is no information regarding the swallowability of these capsules in younger children, DGIEP in consultation with PMHS and PeRC has determined that the pediatric approval of Delzicol will be limited to children 12 years and above.

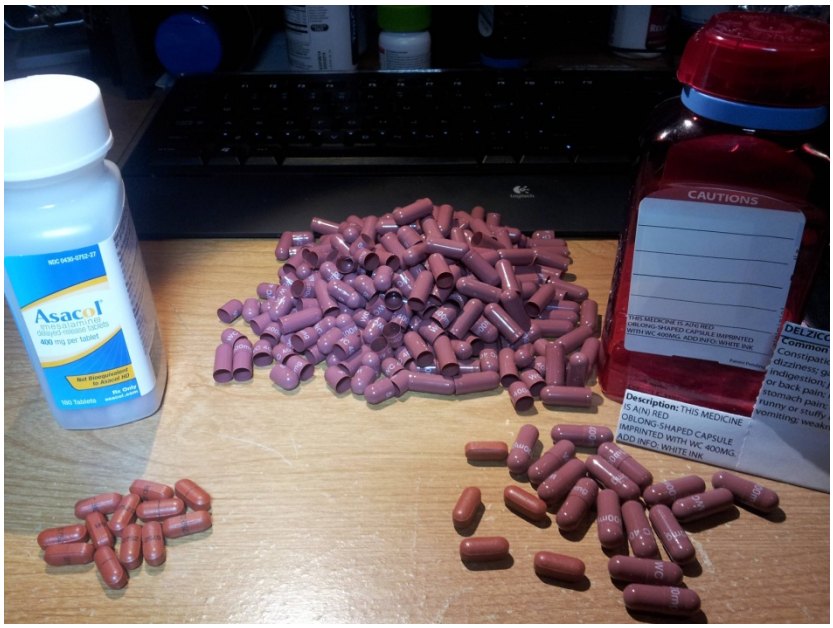
121. Shortly after Delzicol's® release in the spring of 2013, doctors and patients quickly realized that Delzicol® is essentially an Asacol® (400mg) tablet surrounded by an unnecessary capsule. Patients felt deceived and angry that Warner Chilcott was interfering with their health to game the FDA regulatory system and state substitution laws in order to maximize its bottom line.

122. An Oregon newspaper, The Bend Bulletin, recognized the extreme similarity between the drugs and posted a video on YouTube.com. The video depicts schoolteacher Erin Matlock shaking and then opening a Delzicol® capsule, only to find a red tablet that appears identical to "what she was taking before" (meaning Asacol® (400mg)). Bend Bulletin, *Delzicol: How new is it?*, https://www.youtube.com/watch?v=eNtahEEygHI. *See also*, *Delzicol Replacing Asacol*, https://www.youtube.com/watch ?v=oIUYFg7wGj8.

123. Similarly, an ulcerative colitis patient posted the following picture on www.redditt.com under the headline "Opened a Delzicol 'capsule' today because it sounded pretty rattly. …why?":

http://www.reddit.com/r/pharmacy/comments/1fuhxm/opened_a_delzicol_capsule_today_because_it/. The picture appears to depict a 400 milligram Delzicol® capsule separated into two pieces, a capsule and a tablet. The tablet inside the Delzicol® capsule appears to be a solid red Asacol® (400mg) tablet, with the absence of the black lettered pill imprint as the only difference.

124. Another ulcerative colitis patient created a thread discussion page entitled "The difference between asacol and delzicol," posting the following photograph:



The difference between asacol and delzicol., http://www.reddit.com/r/CrohnsDisease/comments/1cbvel/the_difference_between_asacol_and_delzicol/. The Delzicol® tablets on the right appear identical to the Asacol® (400mg) tablets on the left, except they do not have the pill imprint "0752 DR," which was the imprint on Asacol® (400mg) tablets. *See* http://www.drugs.com/imprints/0752-dr-18756.html.

125. Many ulcerative colitis patients were angry that Warner Chilcott (and later Allergan) had deceived them regarding their own medical treatment. A patient on another ulcerative colitis board expressed his frustration:

> ==========
> READ THIS AND BE SHOCKED OR HORRIFIED
> ==========
>
> Delzicol = Asacol. Delzicol - the 'new' medication - is nothing more than a 400 mg Asacol tablet in a dissolving capsule. open it up and see.
>
> I used to get 240 tablets for a $20 co-pay - 8 times a day for 30 days. I just paid $170 for 60 tablets to be taken twice a day.
>
> AN ACT OF FRAUD HAD BEEN COMMITTED.

> Maybe that's not so shocking or horrifying. I guess the pharma companies just don't make enough money. Private jets and golf cost money.

HealingWell.com, May 3, 2013, http://www.healingwell.com/community/default.aspx?f=38&m=2689473&p=6.

126. Warner Chilcott attempted to justify this deception under the pretext that it withdrew Asacol® (400mg) and created Delzicol® due to concerns over DBP, an inactive ingredient in the enteric coating of both Asacol® (400mg) and Asacol® HD.

127. Both Asacol® (400mg) and Asacol® HD have always contained DBP. According to its label, Asacol® (400mg) delivers about 21 mg of DBP per day at the maximum recommended dosage. Asacol® HD contains more than twice as much DBP—delivering 48 mg of DBP per day at the maximum recommended dosage.

128. Back in September 2009, the FDA's Division of Gastroenterology and Inborn Errors Products sent Proctor & Gamble proposed revisions to the Asacol® and Asacol® HD labels that alerted pregnant and nursing mothers about the existence the potentially harmful ingredient—DBP. Both drugs were formerly classified as Pregnancy Category B, the second-safest. Both drugs were then adjusted to Pregnancy Category C, the middle-safest. The new labels were approved May 24, 2010.

129. As indicated by these classifications and the drugs' labels, DBP is a potentially concerning ingredient for pregnant mothers and children, but it is not especially dangerous to the general population. The concern with DBP was summarized on the new Asacol® (400mg) label (emphasis added):

> Dibutyl phthalate (DBP) is an inactive ingredient in Asacol's enteric coating. . . . Published reports in rats show that male rat offspring exposed in utero to DBP (greater than or equal to 100 mg/kg/day, **approximately 39 times the human dose** based on body surface area), display reproductive system aberrations compatible with disruption of androgenic dependent development. The clinical significance of

> this finding in rats is unknown. . . . High doses of DBP, administered to pregnant rats was associated with increased incidences of developmental abnormalities, such as cleft palate (greater than or equal to 630 mg/kg/day, **about 244 times the human dose**, based on body surface area) and skeletal abnormalities (greater than or equal to 750 mg/kg/day, **about 290 times the human dose** based on body surface area) in the offspring.

130. In March 2012, the FDA issued a draft guidance recommending that manufacturers avoid the use of two substances, DBP and di(2-ethylhexyl) phthalate ("DEHP") because research had suggested that these two substances were linked to poor reproductive and developmental outcomes. FDA, *Draft Guidance for Industry on Limiting the Use of Certain Phthalates as Excipients in Center for Drug Evaluation and Research-Regulated Products*, 77 Fed. Reg. 42, 12852 (March 2, 2012).

131. The draft guidance was finalized in December 2012. FDA, *Guidance for Industry: Limiting the Use of Certain Phtalates as Excipients in CDER-Regulated Products* (Dec. 2012). This document concluded:

> Although the current available human data are limited, the Agency has determined that there is evidence that exposure to DBP and DEHP from pharmaceuticals presents a potential risk of developmental and reproductive toxicity. While it is recognized that drug products may carry inherent risks, DBP and DEHP are used as excipients, and safer alternatives are available. Therefore, the Agency recommends that you avoid the use of DBP and DEHP as excipients in CDER-regulated drug and biologic products.
>
> . . .
>
> There are alternatives to DBP and DEHP for use as excipients in CDER-regulated products. Manufacturers with products that contain DBP or DEHP should consider alternative excipients and determine if the alternative excipient they plan to use has been used in similar CDER-approved products and at what level. The Inactive Ingredients Database provides information on excipients present in FDA-approved drug products, and this information can be helpful in developing drug products.
>
> For any currently marketed formulation that includes DBP or DEHP, the applicable Scale-up and Post-Approval Changes (SUPAC) guidances should be referenced to determine the level of change to the formulation and the information (e.g., bridging studies) that should be submitted to support the change. (See, for example, SUPAC

> guidances for industry on Modified Release Solid Oral Dosage Forms (SUPAC-MR, September 1997); Nonsterile Semisolid Dosage Forms (SUPAC-SS, May 1997); and Immediate Release Solid Oral Dosage Forms (SUPAC-IR, November 1995).) . . .
>
> Manufacturers of currently marketed products approved under an NDA or ANDA should refer to the guidance for industry, *Changes to an Approved NDA or ANDA*, for information on the reporting category associated with a change in excipient (FDA guidance for industry April 2004). Questions related to nonapplication drug products should be directed to the appropriate CDER review division.

Id. at 4-5.

132. Warner Chilcott relied on this nonbinding recommendation as a pretext to depict the introduction of Delzicol® as a legitimate step to improve patient safety. Several facts, both before and after the introduction of Delzicol®, establish that Delzicol® is not actually superior to Asacol® (400mg) and was introduced purely to game state and federal law, not to improve patient safety.

133. *First*, Warner Chilcott was not required to remove Asacol® (400mg) from the market to remove DBP from the product. As shown above, the FDA recommended that manufacturers replace DBP with another excipient[21] and then provide the FDA with the necessary regulatory submissions to make sure the new excipient is generally safe and effective. Warner Chilcott could have simply removed the DBP from Asacol® (400mg), replaced it with DBS, and then submitted the necessary information to the FDA. But replacing the excipient would not have given Warner Chilcott the opportunity to exclude competition through additional patent protection on a new product. So instead, Warner Chilcott removed Asacol® (400mg) from the market entirely and then introduced Delzicol® without DBS. The company made sure to include a new, patentable capsule on Delzicol® to give the product additional patent

[21] An "excipient" is a non-active ingredient, typically referred to as "fillers," "diluents," or "bulking agents."

protection. In short, Warner Chilcott's could have removed DBP from Asacol® (400mg), as recommended by the FDA, without removing the product, but it chose not to; instead, it introduced a new patent protected product while simultaneously destroying the market for the product (Asacol® (400mg)) that faced imminent generic competition.

134. *Second*, the DBP warnings primarily applied to pregnant and nursing women as well as young children. As of May 2010, Asacol's label already recommended that Asacol "should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus" and that "[c]aution should be exercised when Asacol is administered to a nursing woman." Similarly, the May 2010 label that the "[s]afety and effectiveness of Asacol tablets in pediatric patients have not been established." In other words, the two small groups of patients potentially most affected by DBP were either not supposed to be taking the drug or no evidence supported the drug's use in that population.

135. *Third*, Warner Chilcott's foreign subsidiary, Warner Chilcott Canada Co., continued to sell Asacol® (400mg) and Asacol® HD ("Asacol® 800") containing DBP to Canadian patients as of December 29, 2014. The company would have introduced DBP-free versions of these products if removing this ingredient resulted in a superior product.

136. *Fourth*, the minor concerns with DBP had been known since at least the 1990s. If Warner Chilcott or its predecessor, Proctor & Gamble, were legitimately concerned with this issue, they would not have introduced Asacol® HD—which also contains even more DBP than Asacol® (400mg)—in 2008 after the potential concerns were well-known.

137. *Fifth*, if Warner Chilcott was concerned about exposure to DBP, it would have first developed a replacement for Asacol® HD, which contains 48 mg of DBP at the

recommended dose, rather than a replacement for Asacol® (400mg), which contains 21 mg of DBP at the recommended dose.

138. *Sixth*, Warner Chilcott continued to give Asacol® (400mg)—containing DBP—to children as part of pediatric clinical trials as late as March 2011. According to www.clinicaltrials.gov, Warner Chilcott sponsored clinical trial NCT00713310 entitled "Assessing the Safety/Efficacy of Asacol® Given Every 12 Hours to Children and Adolescents with Active Ulcerative Colitis," which continued until March 2011, well *after* concerns over DBP were well-known.

139. *Seventh*, Warner Chilcott would not have undertaken extraordinary efforts, including off-label marketing and illegal kickbacks to get patients to switch from Asacol® (400mg) to Asacol® HD—the latter having over twice the amount of DBP—before the patents expired on Asacol® (400mg) if the company was legitimately concerned about DBP exposure.

140. *Eighth*, Warner Chilcott sought, and the FDA approved, the use of Asacol® (400mg) for children on October 18, 2013, *long after Warner Chilcott had removed Asacol® (400mg) purportedly over concerns with DBP*. The FDA granted pediatric approval of Asacol® with full knowledge of the DPB issue, and even referenced DBP concerns in the pediatric approval documents. From October 18, 2013 forward, Asacol® (400mg) has been approved for the treatment of ulcerative colitis in children, despite the presence of DBP.

141. Thus, the totality of the Warner Chilcott's ostensible "concern" with DBP can be summarized as follows:

a. First, in 2009, Warner Chilcott purchased the rights to two mesalamine formulations despite the fact that both these drugs contained DBP, which had been known as a potentially concerning ingredient since at least the 1990s.

b. Next, from 2009 through 2012, Warner Chilcott aggressively pushed patients to the mesalamine formulation that contained more than twice as much DBP as the originator drug.

c. Then, in mid-2012, Warner Chilcott submitted an NDA to replace only the drug that contained half as much DBP, right before that drug was slated to face generic competition.

d. Finally, Warner Chilcott removed the original drug, purportedly out of concern for patient safety, which coerced thousands of ulcerative colitis patients to the product that contains more than twice as much DBP.

E. The "Hard Switch" – Killing the Market for Asacol® (400mg)

142. Even after introducing and aggressively marketing two slightly altered mesalamine products, most of Warner Chilcott's ulcerative colitis patients remained on Asacol® (400mg) and would have remained so until after patent expiration in July 2013. That is, even with the field tilted toward Asacol® HD and Delzicol®—given Warner Chilcott's marketing campaigns—customers still clearly preferred Asacol® (400mg) to the new formulations. As a result, Warner Chilcott was expected to lose 80-95% of the Asacol® (400mg) sales to generic competition within one year of patent expiration, as intended by the Hatch-Waxman act and state generic substitution laws.

143. With nowhere left to turn, Warner Chilcott discontinued Asacol® (400mg) in March 2013, eliminating the market for Asacol® (400mg) and forcing thousands of ulcerative colitis sufferers to immediately find new medications. This "hard switch" finally eliminated the likelihood that a generic company would finalize and release a generic product that could be automatically substituted for brand Asacol® (400mg) prescriptions; that was the intention and effect of Warner Chilcott's anticompetitive product hop scheme.

144. Warner Chilcott knew that even with Asacol® HD and Delzicol® on the market, most patients would remain on Asacol® (400mg) if given the choice. It is well-known that ulcerative colitis patients generally remain on a successful treatment for long periods to avoid the risks associated with switching to a new drug. During a January 2012 conference call, Warner Chilcott's Executive Vice President, Paul Herendeen, acknowledged this feature of the mesalamine prescription market:

> Next let me comment on Asacol. **Asacol is like a battleship. It is hard to change the trajectory of this brand all that much as the market turns over so slowly.** The good news is that this battleship is moving in the right direction, up. Asacol units are relatively steady, and we are able to enjoy growth driven by improved net pricing. So we expect Asacol to fall into the grower category in 2012, and thereafter.

Warner Chilcott CEO Discusses 2012 Guidance (Transcript), January 27, 2012, *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript (emphasis added).

145. Warner Chilcott knew that most patients would have remained on Asacol® (400mg) and then switched to a generic version of the drug if given a choice, so Warner Chilcott decided to eliminate that choice. In March 2013, Warner Chilcott stopped selling original Asacol® (400mg), only a few months before a generic Asacol® (400mg) would have been available in July 2013.

146. It is universally known within the pharmaceutical industry that the reference product must be on the market for the generic drug to gain initial market share. This is because generic companies rely on automatic substitution for brand drugs at the pharmacy counter to gain sales and successfully compete, as explicitly encouraged by payers, state substitution laws, and the Hatch-Waxman Act. *See New York v. Actavis*, PLC, No. 14 CIV. 7473, 2014 WL 7015198, at *9 (S.D.N.Y. Dec. 11, 2014) ("The substitution of AB-rated generic drugs for the branded

equivalents, through the applicability of state generic substitution laws, is the only method by which generic drugs achieve significant sales."). Thus, Warner Chilcott was keenly aware that discontinuing Asacol® (400mg) would: (a) eliminate generic manufacturers' only viable cost-efficient means of competing for Asacol® sales; and (b) secure continuing monopoly profits for itself by denying consumers the ability to purchase generic mesalamine alternatives for the foreseeable future.

147. Warner Chilcott's CEO acknowledged these anticompetitive effects. In a 2012 conference call, Boissonneault had the following exchange with Douglas Tsao, an employee of Barclay's Capital, and acknowledged the anticompetitive effects of his company's actions:

> Tsao: Just a couple of quick ones on Delzicol. First -- or actually with Asacol. Do you anticipate managed care will retain Asacol on formularies past 2013 to 2015 and beyond?
>
> Boissonneault: That's -- well, the issue is it's not going to be available. So to keep it on the formulary, **it's a hard conversion. We're stopping -- we're going to stop the shipment of Asacol 400 shortly, and it will be all Delzicol. I think they're all familiar with what's going on.** We're making progress on that front. But the issue is they can keep it on the formulary, but there won't be any Asacol 400 around.
>
> Tsao: I guess I was just -- the question -- the reason for my thinking was just given the potential availability of generics coming in 2014 and beyond, if they retain it and they could have it as a therapeutic equivalent, sort of what I was curious is on your perspective.
>
> Boissonneault: Yes, I've never seen just in my experience that once they go to DELZICOL -- I mean, in other words, Delzicol has no substitute. They would have to have a substitute for Delzicol. Even if they kept it on the formulary, physicians -- I mean, our first initiative is to get physicians to write Delzicol. But if they had a generic approved, then they'd have to start promoting their own brand.

Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript (emphasis added).

148. Boissonneault also recognized the anticompetitive effects of removing Asacol® (400mg) at a later time in the same call when responding to another question about a generic coming to market in 2014:

> I think, Chris, historically, we've seen those sorts of things happen. **Generally, the generic company doesn't even get launched because the reference product will be Delzicol. There won't be any Asacol out there.** We've seen that happen with Doryx when the generic company got the product approved and by that time, the product had moved on to, say, to 150 or different, had moved on to a tablet because there really isn't that much business. . . . . And basically, as the reference product has changed and then moved on to either tablet or new dose form, there really isn't much to be substituted there.

Id. (emphasis added). In other words, Warner Chilcott knew that a generic version may never come to market if it removed Asacol® (400mg) prior to generic entry in July 2013. And, even if a generic version did come to market, the prescription base would have been completely eliminated, thus depriving the generic company of its only cost-efficient means of competing for Asacol® (400mg) sales.

149. But for Warner Chilcott's discontinuation of Asacol® (400mg) shortly before its July 30, 2013 patent expiration, at least one generic version of Asacol® (400mg) would have been available to consumers no later than July 31, 2013.

150. There is substantial evidence at least one manufacturer would have introduced generic Asacol® (400mg) shortly after patent expiration.

151. In March 2012, experts on ulcerative colitis and inflammatory bowel disease published a review entitled "Mesalamine in the treatment and maintenance of remission of ulcerative colitis" that examined various mesalamine treatments and came to the following conclusion about this class of medications:

> The patent for the original mesalamine formulation, Asacol, is anticipated to expire in July 2013 in the USA. If generic manufacturers can provide evidence of

> bioequivalence with pioneer formulations, it is likely that in many cases payers will transition to cheaper generic versions of patients with UC.

Maggie Ham and & Alan C. Moss, Expert Rev. Clin. Pharmacol., Author Manuscript, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3314328/.

152. In September 2007, Roxane Laboratories, Inc. ("Roxane") sent Proctor & Gamble and patent-holder Medeva Pharam Suisse AG ("Medeva") a letter giving notice that the company had filed a Paragraph IV Certification with respect to Asacol® (400mg). This meant that Roxane had submitted an ANDA to produce generic Asacol® (400mg) and was claiming the existing patents on Asacol® (400mg) were invalid or would not be infringed. *See* 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("For each [existing] patent, the applicant shall provide the patent number and certify . . . one of the following circumstances: . . . (4) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted. The applicant shall entitle such a certification 'Paragraph IV Certification'.").

153. In October 2007, Medeva and Proctor & Gamble filed suit against Roxane for impending patent infringement. The content of this lawsuit shows that Roxane had already made substantial investments in the development of a generic version of Asacol® (400mg). In January 2011, Roxane was sanctioned by the District Court of New Jersey for failing to disclose a batch of its own production attempts to make a generic version of Asacol® (400mg). *See* Order Granting Mot. Sanctions at 16-36, *Medeva Pharma Suisse A.G., et al, v. Roxane Laboratories,* Inc., No. 07-5165 (Jan. 28, 2011), ECF No. 223. In December 2011, pursuant to stipulation and order of dismissal, Roxane informed the court that it no longer intended to pursue a generic version of Asacol® (400mg) before patent expiration in July 2013.

154. On or about June 22, 2010 Par Pharmaceutical, Inc. ("Par") and EMET Pharmaceuticals, LLC ("EMET") submitted ANDA No. 200-730 for a 400mg mesalamine delayed-release oral tablet intended to be bioequivalent to Asacol® (400mg). In connection with this application, Par sent Warner Chilcott a "Notice of Paragraph IV Certification" letter saying it intended to challenge the validity or applicability of Asacol® (400mg)'s existing patents.

155. On or about October 14, 2010, Indian pharmaceutical company Lupin Limited announced that it had reached an agreement with Warner Chilcott plc and its U.S. subsidiary, Warner Chilcott Company, LLC to settle then outstanding patent litigation regarding two Warner Chilcott products, Loestrin® 24 Fe and Femcon® Fe. As part of the settlement, Warner Chilcott agreed that it would allow Lupin to purchase and dispense an authorized generic version of Asacol® (400mg) if a generic version of the drug was introduced by a third party in the United States. This term of the settlement evidences Lupin Limited's expectation that a generic version of Asacol® (400mg) would be introduced by a third party in subsequent years. In other words, by virtue of a 2010 settlement with Lupin related to other drug litigation, Warner Chilcott had already guaranteed that a second generic Asacol® (400mg) product would enter the market *as soon as* another third party successfully entered the market with a generic Asacol® (400mg) product.

156. On August 9, 2012, Par informed the court that it no longer intended to market a generic version of Asacol® (400mg) prior to the expiration of the applicable patent, and had converted its Paragraph IV Certification into a Paragraph III Certification, meaning that the company intended to release a generic Asacol® (400mg) product upon patent expiration. *See* 21 C.F.R. § 314.94(a)(12)(i)(A)(3). Upon information and belief, Par was not aware that Warner

Chilcott intended to remove the reference product and eliminate the market for Asacol® (400mg) shortly before it intended to launch a generic product the next year.

157. In September 2011, Zydus Pharmaceuticals USA, Inc. along with affiliates indicated that it had submitted a Paragraph III certification with respect to the patents on original Asacol® (400mg). This meant that Zydus agreed to delay its launch of an FDA approved version of Asacol® (400mg) until the drug's patents expired in July 2013.

158. The fact that two companies (Roxane and Par) filed Paragraph IV Certifications challenging the validity of the patents on Asacol® (400mg) and at least two companies (Par and Zydus) filed Paragraph III Certifications with respect to Asacol® (400mg) indicates at least one of these companies would have introduced a generic Asacol® (400mg) immediately after patent expiration in summer 2013. Such entry would have immediately triggered Lupin's rights—secured as part of its Loestrin settlement—to release an authorized generic version of Asacol® (400mg). Thus, in 2012, before Warner Chilcott destroyed the Asacol® (400mg) market, there were at least four generics looking to enter the market upon patent expiration in the summer of 2013.

159. Warner Chilcott's removal of Asacol® (400mg) not only blocked access to a lower-cost generic, it also disrupted, without medical justification, the treatment of thousands of ulcerative colitis sufferers. Warner Chilcott's regulatory games likely caused thousands of patients to experience terrible unnecessary symptoms.

160. By design, Warner Chilcott's "hard switch" denied doctors and patients the right to decide whether the benefits of switching to Asacol® HD or Delzicol® would outweigh the benefits of purchasing a less-expensive generic Asacol® (400mg). The market had already sent a clear message to the Company that doctors and patients preferred Asacol® (400mg) to the new

formulations. Warner Chilcott's "hard switch" effectively destroyed the market for generic Asacol® (400mg).

F. Warner Chilcott Moves Patients to Asacol® HD and Delzicol®

161. Warner Chilcott was pleased with its removal of Asacol® (400mg) and its launch of Delzicol® in spring 2013. Roger Boissonneault described the ongoing transition in a May 2013 conference call:

> With the groundwork well underway, in mid-March, we began the promotion of Delzicol to physicians. Our gastroenterology and other field sales resources have done a great job of jump starting this important initiative. While it's still early days, I am pleased with the launch strategy of Delzicol and the overall performance of Asacol, Delzicol franchise. The strength of Asacol brand name and excellent managed care coverage have made Asacol HD an additional prescribing option for certain patients during the transition to Delzicol. Again, very early days, but I believe the transition of the franchise is going well.

Warner Chilcott Management Discusses Q1 2013 Results – Earnings Call Transcript, May 10, 2013, *available at* http://seekingalpha.com/article/1423971-warner-chilcott-management-discusses-q1-2013-results-earnings-call-transcript.

162. On October 1, 2013, Allergan plc (then "Actavis plc") acquired Warner Chilcott plc and became the successor in interest to Asacol® (400mg), Asacol® HD, and Delzicol®.

163. Warner Chilcott's successful efforts to thwart generic competition with Asacol® (400mg) were recognized as a high point of the acquisition. The President of Global Generics for Actavis at the time, Sigurdur Oli Olafsson, specifically recognized this fact: "We have been extremely impressed with how Roger and his team have built out, I think, the ever-greening line extension strategy behind the scenes." Actavis' CEO Hosts Acquisition of Warner Chilcott Conference (Transcript), May 20, 2013, *available at* http://seekingalpha.com/article/1447961-actavis-ceo-hosts-acquisition-of-warner-chilcott conference-transcript.

164. Roger Boissonneault and other Warner Chilcott executives were handsomely rewarded by Actavis for this "ever-greening line extension strategy." According to SEC filings, Boissonneault was eligible to receive approximately $24.5 million dollars in "Golden Parachute Compensation" as a result of Actavis plc's acquisition of Warner Chilcott.

165. Warner Chilcott's extensive generic suppression efforts have proven beneficial for Allergan. Allergan continues to sell Asacol® HD and Delzicol® in the United States. The two prescriptions sold approximately $550 million in 2014. This is hundreds of millions more than what sales would have been but for Warner Chilcott's unlawful scheme to foreclose generic Asacol® (400mg) products—which would be the preferred formulation priced at a fraction of the cost of brand Asacol® (400mg), Asacol® HD, and Delzicol®.

166. The legitimacy of the Delzicol® patent has also recently been challenged. In August 2015, two Warner Chilcott subsidiaries filed suit against two Teva Pharmaceuticals entities after Teva filed a Paragraph IV ANDA seeking FDA approval to market a generic version of Delzicol because the drug's sole patent (U.S. Patent No. 6,649,180) is either invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of a generic version of Teva's generic Delzicol® product.

167. Mylan Pharmaceuticals Inc. also recently announced that it had filed a Paragraph IV ANDA certification challenging the validity of the sole Delzicol® patent. Mylan reports that two Warner Chilcott subsidiaries have filed suit against the company in the U.S. District Court for the Eastern District of Texas and that this litigation is currently pending.

168. As the "product hopping" scheme unfolded, Warner Chilcott (and then Allergan) found the scheme at risk from a new threat: imminent AB-rated generic competition for the Asacol® HD product that the Companies worked so hard to maximize via the product hop.

169. On September 26, 2011, Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited filed ANDA No. 203-286 seeking FDA permission to sell a generic version of Asacol® HD. Zydus filed a Paragraph IV Certification, which meant that it intended to challenge the validity or applicability of the patents on Asacol® HD. After two years of litigation, Warner Chilcott and Zydus announced a settlement agreement in December 2013. Under the publicly-disclosed terms of the agreement, the companies claimed that Zydus will receive an exclusive royalty-bearing license to market Asacol® HD on November 15, 2015, if Zydus receives FDA approval by that time. If Zydus does not receive the necessary FDA approval, Warner Chilcott would permit Zydus to market an authorized generic version of Asacol® HD on July 1, 2016.

G. Deja-vu: Delzicol® HD Product Hop May Be "Coming Soon"

170. In a January 31, 2014 investor presentation, Allergan (then "Actavis") stated that it intended to submit a NDA for "Delzicol® 800mg" sometime in 2014. The company expected this new product to receive FDA approval and be launched in 2015. Upon information and belief, no "Delzicol® 800mg" product has been approved as of the filing of this Complaint.

171. The launch of Delzicol® 800mg would have allowed Allergan to switch patients to this new formulation immediately before a generic version of Asacol® HD comes to market. As a result, consumers who were originally on Asacol® (400mg) and were forced to switch to Asacol® HD will likely be switched again to another "new," practically identical mesalamine brand product, before Zydus or another generic Asacol® HD manufacturer can enter the market.

VI. CLASS ACTION ALLEGATIONS

172. Plaintiffs bring this action on behalf of themselves and all others similarly situated under Fed. R. Civ. P. Rules 23(a) and (b)(3), as defined below.

> All persons or entities in the United States and its territories that purchased or paid for some or all of the retail purchase price for Asacol® (400mg), Asacol® HD, and/or Delzicol® prescriptions, for consumption by themselves, their families, or their members, employees, or insureds in Arizona, California, District of Columbia, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, or Wisconsin, at any time between July 31, 2013 until the anticompetitive effects of Warner Chilcott and Allergan's conduct cease (the "End-Payor Class").[22]

173. The following persons or entities are excluded from the proposed End-Payor Class:

a. The Defendants and their officers, directors, management, employees, subsidiaries or affiliates;

b. All governmental entities, except for government funded employee benefit plans;

c. All persons or entities who purchased oral mesalamine prescription drugs for the purposes of resale or directly from Product Hop Defendants and their affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another entity that covered 100% of the Plan's reimbursement obligations to its members);

e. Pharmaceutical Benefit Managers; and

f. The judges in this case and any members of their immediate families.

174. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe the Class includes hundreds of thousands, if not millions, of consumers and thousands of third-party payers.

175. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants. Class

[22] In accordance with the Court's July 20, 2016 Order, the Proposed End-Payor Class no longer includes Hawaii and Utah purchasers and no longer includes non-consumer purchasers in Massachusetts, Missouri, or Vermont.

members paid artificially inflated prices for brand mesalamine formulations as a result of Product Hop Defendants' unlawful conduct and were deprived of the opportunity to purchase less-expensive generic Asacol® (400mg).

176. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests coincide with those of the Class.

177. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

178. Questions of law and fact common to the members of the Class predominate over questions that affect individual class members because virtually all of the legal and factual questions in the case center on Defendants' conduct and Defendants' conduct affected the entire class similarly.

179. Questions of law and fact common to the Class include:

a. Whether Product Hop Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether Product Hop Defendants' anticompetitive scheme suppressed market entry of generic Asacol® (400mg) drug products;

c. Whether Product Hop Defendants' introduction of Delzicol® and destruction of the Asacol® (400mg) prescription base was predatory and anticompetitive;

d. Whether Product Hop Defendants withdrew Asacol® (400mg) out of legitimate safety concerns or for predatory and anticompetitive reasons;

e. Whether Product Hop Defendants surrounded Asacol® (400mg) with a capsule and renamed it Delzicol® for precompetitive reasons or for the anticompetitive purpose of thwarting generic competition;

f. Whether there are cognizable, non-pretextual, precompetitive justifications for Product Hop Defendants' conduct that could not be accomplished in a less restrictive manner;

g. Whether direct proof of anticompetitive effects or Product Hop Defendants' monopoly power is available, and if proof of monopoly power is required and available, whether it is sufficient to prove anticompetitive effects without the need to also define a relevant market;

h. What are the relevant market or markets, to the extent that these markets need to be defined;

i. Whether Product Hop Defendants' scheme, in whole or in part, has substantially affected interstate and intrastate commerce;

j. Whether Product Hop Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Class; and

k. The quantum of overcharges paid by the End-Payor Class in the aggregate.

180. Proceeding on a classwide basis is a superior method for the fair and efficient adjudication of the controversy because class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expenses that individual actions would entail. Class treatment will allow injured persons and entities to seek compensation for injuries that would not be practical to pursue individually. These benefits substantially outweigh any difficulties that may arise out of class treatment.

181. Plaintiffs do not know of any legitimate reason that this action cannot be pursued as a class action.

VII. EFFECT ON INTERSTATE AND INTRASTATE COMMERCE

182. Asacol® (400mg), Asacol® HD, and Delzicol® were sold by Product Hop Defendants across state lines at all relevant times..

183. Contracts, bills, and other forms of business communications pertaining to Asacol® (400mg), Asacol® HD, and Delzicol® were transmitted in a continuous and uninterrupted flow across state lines in the exchange of intrastate and interstate commerce.

184. Defendants' anticompetitive conduct occurred in part in trade and commerce within the states set forth herein. Defendants' conduct had substantial interstate and intrastate effects because retailers within each state have been foreclosed from offering cheaper generic versions of Asacol® (400mg) and Asacol® HD. This directly impacted and disrupted commerce for end-payors within each state who have been forced to continue to pay *supra*-competitive prices. The End-Payor Class would have paid less for their oral mesalamine prescriptions by purchasing generic Asacol® (400mg) had one been available.

VIII. MARKET POWER

185. At all relevant times, Warner Chilcott and Allergan had monopoly power in the market for Asacol® (400mg) because they had the power to raise or maintain the price of Asacol® (400mg) at *supra*-competitive levels without losing enough sales to make *supra*-competitive prices unprofitable.

186. At all relevant times, Warner Chilcott and Allergan had monopoly power in the market for Asacol® HD because they had the power to raise or maintain the price of Asacol® HD at *supra*-competitive levels without losing enough sales to make *supra*-competitive prices unprofitable.

187. At all relevant times, Warner Chilcott and Allergan had monopoly power in the market for Delzicol® because they had the power to raise or maintain the price of Delzicol® at *supra*-competitive levels without losing enough sales to make *supra*-competitive prices unprofitable.

188. Upon information and belief, there is direct evidence of anticompetitive effects and market power available in this case sufficient to show Warner Chilcott and Allergan's ability to control the prices of Asacol® (400mg), Asacol® HD, and Delzicol®, and exclude relevant competitors, without the need to show relevant antitrust markets. Upon information and belief,

direct evidence consists of, among other things: (A) the fact that generic versions of Asacol® (400mg) and Asacol® HD would have entered the market at substantial discounts to the brands, sooner, but for the Defendants' anticompetitive conduct; (B) the gross margins on brand Asacol® (400mg), Asacol® HD, and Delzicol® were at all times substantial enough to show market power, with prices at least 60% higher than costs of production; and (C) Defendants never lowered the price of Asacol® (400mg), Asacol® HD, or Delzicol® in response to the pricing of other brand or generic drugs.

189. To the extent that Plaintiffs are required to prove monopoly power by defining a relevant product market, Plaintiff alleges that there are three relevant antitrust product markets: (1) Asacol® (400mg) and its AB-rated bioequivalent generics; (2) Asacol® HD and its AB-rated bioequivalent generics; and (3) Delzicol® and its AB-rated bioequivalent generics. The Product Hop Defendants have unlawfully maintained monopolies in all three markets by destroying market one (Asacol® (400mg)) to increase sales volume in markets two and three (Asacol® HD and Delzicol®).

190. A small but significant, non-transitory price increase in the price of Asacol® (400mg) would not have caused a significant loss of sales. At competitive prices, Asacol® (400mg) does not exhibit significant, positive, cross-elasticity of demand with respect to price with any other mesalamine formulation or treatment for ulcerative colitis other than AB-rated generic versions of the product.

191. A small but significant, non-transitory price increase in the price of Asacol® HD would not have caused a significant loss of sales. At competitive prices, Asacol® HD does not exhibit significant, positive, cross-elasticity of demand with respect to price with any other

mesalamine formulation or treatment for ulcerative colitis other than AB-rated generic versions of the product.

192. A small but significant, non-transitory price increase in the price of Delzicol® would not have caused a significant loss of sales. At competitive prices, Delzicol® does not exhibit significant, positive, cross-elasticity of demand with respect to price with any other mesalamine formulation or treatment for ulcerative colitis other than AB-rated generic versions of this product.

193. Defendants only needed to control Asacol® (400mg) and its AB-rated generic equivalents, and no other products, in order to maintain the price of the product profitably at *supra*-competitive prices. Only the market entry of a competing, AB-rated generic version of Asacol® (400mg) would have rendered Defendants unable to profitably maintain *supra*-competitive prices for this product.

194. Defendants only needed to control Asacol® HD and its AB-rate generic equivalents, and no other products, in order to maintain the price of the product profitably at *supra*-competitive prices. Only the market entry of a competing, AB-rated generic version of Asacol® HD would render Defendants unable to profitably maintain *supra*-competitive prices for this product.

195. Defendants only needed to control Delzicol® (400mg) and its AB-rate generic equivalents, and no other products, in order to maintain the price of the product profitably at *supra*-competitive prices. Only the market entry of a competing, AB-rated generic version of Delzicol® would render Defendants unable to profitably maintain *supra*-competitive prices for this product.

196. Defendants sold brand Asacol® (400mg), Asacol® HD, and Delzicol® in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

197. Due to unique characteristics in the pharmaceutical market, including, among other things, switching costs and a price disconnect between prescribers and payers (*i.e.*, consumers and third-party payors), price sensitivity is severely dampened between different prescription drugs, except for AB-rated generics and their respective brand equivalent.

198. The United States and its territories constitute the relevant geographic market.

199. At all relevant times, Defendants enjoyed high barriers to entry with respect to the above-defined relevant markets due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

200. Defendants' market share in the relevant markets was and remains to be 100%.

IX. CLAIMS FOR RELIEF

COUNT I

Monopolization Under State Law
(Product Hop Defendants: Allergan and Warner Chilcott)

201. Plaintiff incorporates the preceding paragraphs as though fully set forth herein.

202. At all relevant times, Product Hop Defendants possessed substantial market power (*i.e.* monopoly power) in the relevant markets for Asacol® (400mg), Asacol® HD, and Delzicol®. Defendants possessed the power to raise and maintain *supra*-competitive prices and exclude competitors from the relevant markets. Product Hop Defendants intentionally destroyed one market in order to stave off competition and force consumers to their other product markets.

203. Through the Product Hop scheme described above, Product Hop Defendants willfully maintained and continue to maintain monopoly power in the relevant markets using

restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured Plaintiff and members of the End-Payor Class. Specifically, by destroying the Asacol® (400mg) market, Product Hop Defendants excluded generic Asacol® (400mg) competitors and denied Plaintiff and members of the End-Payor Class the opportunity to purchase Asacol® (400mg) at a substantial discount. Product Hop Defendants' motive for destroying their own monopoly market in Asacol® (400mg) was the fact that the destruction and attendant exclusion of competitors in that market would force consumers to the Defendant-controlled Asacol® HD and Delzicol® markets, which faced no imminent threat of generic competition.

204. Product Hop Defendants' conscious objective was and is to exclude generic competition through the anticompetitive scheme described above.

205. Product Hop Defendants' anticompetitive scheme harmed competition and consumers as alleged above. But for Product Hop Defendants' conduct, Plaintiffs and the End-Payor Class would have paid less for generic Asacol® (400mg) than they have been forced to pay for Asacol® HD and Delzicol®.

206. There are no non-pretextual procompetitive justifications for Defendants' conduct. Even if there were such conceivable justifications, the anticompetitive effects of Product Hop Defendants' conduct far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive justifications.

207. Product Hop Defendants' anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiff and the Class, as described herein.

208. By engaging in the conduct described above, Product Hop Defendants intentionally and wrongfully maintained monopoly power in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. Iowa Code §§ 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

f. Mass. Gen. L. Ch. 93A, §1 *et seq.*, with respect to purchases in Massachusetts by members of the Class.

g. Me. Rev. Stat. Ann. Tit. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

h. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

i. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

k. Mont. Code Ann. §§ 30-14-205, *et seq*. with respect to purchases in Montana by members of the Class.

l. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by members of the Class.

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases in Nevada by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases in New Hampshire by members of the Class.

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases New Mexico by members of the Class.

q. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by members of the Class.

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

u. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchase in Rhode Island by members of the Class.

v. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

w. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

x. Vt. Stat. Ann. Tit. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

y. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

z. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.[23]

[23] In accordance with Court's July 20, 2016 Order, End-Payor Plaintiffs no longer pursue claims under Utah and Hawaii law.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully pray that the court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3); direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Class; and declare that Plaintiffs are the representatives of the End-Payor Class;

B. Enter joint and several judgments against Defendants and in favor of Plaintiffs and the Class;

C. Declare the acts alleged herein to be unlawful under the state statutes set forth above;

D. Award Plaintiffs damages as provided by law in the amount to be determined at trial;

E. Award the Class damages and, if applicable, treble, multiple, punitive and/or other damages, in the amount to be determined at trial, including interest;

F. Award Plaintiffs and the Class the costs of this suit, including reasonable attorneys' fees as provided by law; and

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct as the Court deems appropriate.

XI. JURY DEMAND

209. Pursuant to Fed. R. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: August 15, 2016

Respectfully submitted,

/s/ Nathaniel L. Orenstein

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CERTIFICATE OF SERVICE

I, Nathaniel L. Orenstein, hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 15, 2016.

/s/ *Nathaniel L. Orenstein*
Nathaniel L. Orenstein